UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,408	06/27/2003	Brian R. Will	WILB01	8452

7590 04/11/2007

Kurt M. Rylander
Rylander & Associates, P.C.
406 West 12th Street
Vancouver, WA 98660

EXAMINER	
SHAY, DAVID M	
ART UNIT	**PAPER NUMBER**
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,408	WILL, BRIAN R.	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on January 16,2007

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2007 has been entered.

Applicant has sworn an affidavit under 37 C.F.R. 1.132, which will be analyzed here. Affiant first states, after noting that the Affidavit is in response to the office action of July 14, 2006, that affiant is a board certified Ophthalmologist with 17 years experience; has performed thousands of surgeries; and is familiar with devices such as those in the applied art. It is also noted that affiant makes reference to the experience of others, who are not signatories to the affidavit. As such, the opinions of these others are of little moment.

Affiant then asserts, in paragraph 3, that the invention provides improved accuracy of surgery due to reduced distortion of the eyeball and greater precision of positioning, as well as other improvements related to the results of the surgery. The examiner notes affiant's assertions.

Affiant goes on to assert, in paragraph 4, that the criss-cross channel design affords various advantages, including (a) the prevention of "rocking" by provision of "multiple contact points spread over a wider surface, preventing the cornea, sclera, and conjunctiva from being displaced into the vacuum channels and providing a more stable contact"; (b) "prevent occlusion of the vacuum source"; (c) "markedly reduces deformation of the eye"; (d) as opposed to a vacuum annulus, distributes the vacuum and thus "creates a lower profile device thereby obviating the need to use a lid speculum"; (e) the device is easily repositonable "because the criss-cross channels do not cause gross distortion of the cornea, sclera, and conjunctiva, whereas

existing devices prevent repositioning due to the indentation and elevation of a ring of tissue on the cornea, sclera, and conjunctiva when conventional fixation devices are removed"; (f) "shallow criss cross channels allow[s] for more rapid and thorough cleaning of the apparatus, providing quicker turnaround time between patients and extending the life of the devices themselves"; (g) "X-Y translation guides...provide adjustment capabilities built in to the fixation device which allow for superior centration"; and (h) "docking screws...for docking surgical devices into the fixation aperture, rather than the conventional pincer type docking systems provide smoother docking with less manual dexterity required".

While affiant's assertions are noted, the examiner is not convinced by the assertions above. It is presumed, although nowhere specifically stated that the affidavit is directed to a device such as claimed in the instant claims, in contrast to devices constructed in accordance with the teachings of L'Esperance (EP '127) or Hellencamp. However, many of the comments appear to be directed to comparing the claimed device to a type of suction ring that Hellencamp describes as prior art: the suction ring wherein the only eye contact surfaces consist of two concentric circular walls contacting the eye, between which a vacuum is applied (herein after "the concentric ring wall contact fixation ring"). As to (a), it is noted that the devices of L'Esperance (EP '127) and Hellencamp both provide "contact points spread over a larger surface" than the concentric ring wall contact fixation ring, and further L'Esperance (EP '127) arguably and Hellencamp certainly provides "contact points spread over a larger surface" than the instant device. As to (b), the occlusion prevention – an apparent effect of the reduced opening size compared to the concentric ring wall contact fixation ring (affiant gives no other theory upon which such a claim would be predicated) – would also be present in at least the

Hellencamp device, and also, arguably in the L'Esperance (EP '127) device. With regard to (c), once again, no particular structure is theorized as responsible for the advantage, however, the advantage presumably flows from the smaller aperture through which the vacuum is drawn (creating greater flow resistance with proportional pressure drop), a result which would also be present in the devices of L'Esperance (EP '127) and Hellencamp. Concerning (d), while it is not clear why the use of the "vacuum annulus" (i.e. the concentric ring wall contact fixation ring), fails to afford the "low profile", it would stand to reason that the devices of L'Esperance (EP '127) and Hellencamp would similarly provide this advantage, as these do not provide a "vacuum annulus" either. Regarding (e), as the devices of L'Esperance (EP '127) and Hellencamp do no provide vacuum through an unobstructed annulus, they too would exhibit this advantage. As for (f), the device of L'Esperance (EP '127) would provide this, by dint of the resilient member which would prevent the flow of mucous into the vacuum passages, and that of Hellencamp is specifically disclosed as providing this advantage (see column 5, lines 22-50). In regards to (g) it is respectfully noted that while guides are claimed, there is not specific recitation of X-Y translation guides. With respect to (h), it is respectfully noted that applicant's "docking screws" appear to be, in essence, set screws, and set screws are a notorious mechanical expedient for maintaining the relative alignment and otherwise arresting the position of two elements.

In paragraph 5, affiant asserts that the "criss-cross channel design allows a lower vacuum setting to achieve the same fixation of the eye" and alleges that the rings of Curtin and Hellencamp "displace significant amounts of tissue". The examiner notes that while affiant's assertions may be true for the concentric ring wall contact fixation ring devices, such as the device of Curtin, the device of Curtin has never been put forth as teaching a structure similar to

applicant's criss-cross channels. However, the device of Hellencamp includes an insert which prevents the degree deformation of the cornea which would occur, were element 40, the suction enhancement assembly not in place. Thus, while affiant's evaluation of the performance of the Hellencamp device is noted, the examiner can see no structure which would cause it to behave in the manner described by affiant. As such, it is clear that the Hellencamp device will not deform the cornea to the degree the concentric ring wall contact fixation ring devices of Curtin would. This is also evidenced by the Hellencamp disclosure, which specifically states that the device "would ideally prevent the effects of chemosis" (see column 4, lines 29-30). With respect to paragraph 5(b), affiant asserts that the spaced channels serve to "pull the corneal, scleral, and conjunctival surface taut between them and provide many lands". Given the structure of the Hellencamp suction enhancement device, which provides spaced apart ports, with intervening lands, the same advantages would also apply thereto. Affiant also discusses the "annular vault" of L'Esperance (EP '127) necessitating the use of a lid speculum. However, it is not clear to the examiner why one would follow from the other.

In paragraph 5(c), affiant describes various effects relating to the deformation of the cornea caused by "annular vacuum rings". However, while affiant asserts that various effects are "important factors in less than optimal surgical outcomes", there is no nexus presented between the transient effects such as reduced pupillary response and the non-optimal outcomes. Similarly, in paragraphs 5(d) through (g) affiant describes eye distorting effects produced by "high vacuum". However, as the claims at bar make no reference to any particular level of vacuum, this does not distinguish the claimed invention over the applied art. Affiant also continues, in paragraph 5(h), to theorize the inability of the device of L'Esperance (EP '127) to

perform its function, as before, these unsupported assertions are not convincing and applicant's attention is respectfully invited to the office action mailed July 14, 2006, page 2 thereof. While affiant asserts that there is no assertion that e.g. L'Esperance (EP '127) "is non-functioning or invalid" the examiner must note that even though this is not stated *ipsis verbis*, arguing that the porous membrane would clog necessarily means that the inevitable loss of fixation must then occur as a result of the clogging.

With regard to the statement in paragraph 6, the examiner notes affiants statement. Regardless of the issue of certain effects being properly termed operation or complication, the fact still remains, applicant's arguments hinge on the L'Esperance device being unable to function to fix the eye due to clogging of the porous element.

With regard to Paragraph 7, affiant appears to be under the impression that the examiner believes that there are, in actuality, no problems with the prior art. The examiner apologizes for any misunderstanding. What the examiner was attempting to convey was that there is no showing that the problems outlined by applicant are present in the devices of Hellencamp and L'Esperance (EP '127), not that they were not present in the prior art, e.g. reduced corneal hydration. However, affiant's lack of express statement that eye fixation devices as disclosed by Hekkancamp and L'Esperance (EP '127) do little to remedy this lack of showing. The article cited by is affiant (Liu et al) in paragraph 7 is not available to the examiner, however an abstract thereof was located on line. This abstract did not indicate that eye fixation devices as taught by Hellancamp or L'Esperance (EP '127) were used in any of the procedures.

In paragraph 8, affiant asserts that the "low profile" eliminates the need for a lid speculum in many cases. It is not clear to the examiner why this is necessarily the case, since the

function of a lid speculum is to retain the lid in an open position. It would appear that a "high profile" device would accomplish this effect, by preventing the lid from riding up over the device. Affiant also asserts that higher rates of complications due to the use of annular fixation devices on patients with narrow ocular fissures, such as those of Asian decent. Subsequently, affiant states that dry eye, according to another article (Albietz et al) "was likely due, in part, to damage from the vacuum fixation apparatus". The examiner was unable to obtain this article, however, an abstract thereof, though discussing various factors contributing to the greater incidence of dry eye in patients of Asian decent, did not discuss damage from the use of fixation rings. The examiner has included an article discussing the damage to the corneal neural plexus during flap formation as the cause of dry eye after LASIK. In any event affiant postulates that this is in part due to the "fewer stresses" applied to the cornea by the instant device. This appears to be a function of the reduced vacuum level, which is not part of the claimed invention. Affiant also credits the "low profile, conforming base, which fits under the eyelid" for this boon. However, there is nothing that would prevent a low profile from being formed in an fixation device with an annular chamber so that the jutted out from the annular chamber so as to form a low profile portion, thus this is not a consequence of the criss cross configuration of the channels.

In paragraph 9, affiant states that, with regard to the L'Esperance references of record that they "all share the drawbacks of the high profile and difficult cleaning of other annulus apparatus". However, the examiner must respectfully note that porous membrane of the L'Esperance references forms a portion of the device which is only slightly above the surface of the eye and extends beyond the edge of the annular chamber, and it is unclear why, in the device

of applicant, such a structure is "low profile", but in the case of the L'Esperance devices it is not. The protruding membrane portion of the L'Esperance devices would clearly fit under the eyelid just as easily as that of applicant, and thus must also be considered "low profile". With regard to the question of cleaning the device, the difficulty is disclosed as cleaning the internal vacuum passages of the device (see Hellencamp, column 3, lines 45-61). Thus it is not clear how this would be a problem for the L'Esperance devices, if as affiant asserts, the membrane which is exterior to the internal vacuum passages, would be clogged. Affiant then states that "[B]based on my experience, the pores of the L'Esperance design are quite vulnerable to clogging…", however, as the examiner has already noted previously, affiant has nowhere expressly stated that affiant has had any actual experience with this particular type of eye fixation device, this state of affairs is confirmed by affiant's use of the subjunctive in the succeeding subsections of this paragraph. With all due respect, defining the problems of a device which one has never used would appear to be the definition of "speculation". The examiner restates his assertion that, by way of evidentiary showing to the contrary, that L'Esperance, Jr. (US '148) discloses such a structure (see Figure 2 therein), while L'Esperance, Jr. (US '172) incorporates the aforementioned L'Esperance, Jr. (US '148) by reference and specifically claims (see claims 12, 13, and 19 therein) such an eye-fixation means. As these issued US Patents enjoy a presumption of validity, the claimed "annular eye retainer" that is "applied to the cornea for pre operative eye fixation" must, in fact, fix the eye, which requires that the air permeable membrane be designed such that it is not clogged my mucous. Thus theories put forth by affiant as to what "would" happen were a fixation ring with an air permeable membrane of the type disclosed by L'Esperance to be used, rather than what "does" happen when the device is used, are insufficient

to overcome the evidentiary showing put forth by the examiner, and these arguments are not convincing. It is also unclear why the myriad small openings of the membrane of L'Espeance are so prone to complete obstruction, while the single small opening of applicant's device is completely immune thereto. Also as stated above, the protruding portion of the air-permeable membrane constitutes a "low profile" portion and thus also provides all the benefits of any other low profile device.

With respect to paragraph 10, affiant discusses the X-Y translation ability of the instant device, however, affiant only discusses the advantages of this set up with respect to that disclosed by Curtin. While the advantage is noted, this does not serve to distinguish the performance or advantages of the instantly claimed device over one constructed in view of the combined teachings of L'Esperance (EP '127) or Hellencamp in combination with Clark et al, specifically with respect to "a microkeratome **11** with infinite adjustment capabilities" (see Clark et al column 5, lines 11-12, bold type in original). It is further noted that the device of Curtin does provide for total adjustment in all three dimensions, as is evident from the devices allowing the movement associated with elements 20, 28, 38, 60, 74, and 134 in Figure 1 thereof. Thus the need for precise positioning, and mechanical mean including mating threaded structures for producing this positioning were known in the art. These remote adjustment structures, similar to the rmote adjustment structures of Clark et al (e.g. element 177 in Figure 1 of Clark et al) would afford the same advantages, such as unobstructed view and reduced contamination, ascribed to the instant adjustment mechanisms.

With respect to affiant's assertions concerning "existing devices" the examiner respectfully notes that obviousness for the purpose of patentability is determined within the

context of all the knowledge available to one having ordinary skill in the art, not simply those devices currently commonly commercially available. Also, while the examiner appreciates that providing adjustments "in the sub-micron range" would be desirable, it is not clear that the instant device, as originally disclosed, is enabled to provide such a thing. Extremely small threads would provide an excursion of .0138 inches per revolution (this is equivalent to the thread on an NF72 bolt), as contrasted to a micron, which is .00003937 inches. This would require the adjustment nut to be turned through less than .00283 revolutions, or 1.02 degrees of arc in order to achieve sub-micron adjustment. Further, while this may be desirable in the art, it is not expressed in the claims.

Turning now to applicant's arguments, applicant argues that the references do not teach a "a convex bottom contact portion, without use of a vacuum annulus, nor do they disclose apparatus or methods capable of repositioning a vacuum-based eye fixation apparatus after vacuum has been applied initially." The examiner firstly notes that while neither L'esperance nor Hellencamp provide "a convex bottom contact portion", neither does the instant device, these devices all provide concave contact portions, which are, in the words of L'Esperance, "contoured to engage and retain the eye" (see column 4, lines 30-31). Secondly, no exclusory proviso in the instant claims requires the device to be made or used "without use of a vacuum annulus". Thus neither of these consiuderations applies to the art as it is applied to the claims at bar.

Applicant then states the "criss-coss channels, providing alternating lands grooves, are fundamental to the present invention", however, there has been no showing of the criticality of this particular arrangement of voids and barriers. It is not clear to the examiner how the alternating pores and barriers (lands), made up of the walls of the pores, in L'Esperance; or how

the distributed voids of Hellencamp, would produce any more of a raised area (termed a "hickey" in the affidavit) than the instant grooves. Clearly an unobstructed vacuum ring such as taught by Curtin, would produces a raised annulus which would render repositioning the ring in a slightly different place more difficult. But it appears to the examiner that the degree of deformation of the sclera due to the exposure to vacuum would be the result of a combination of the level of vacuum, the stiffness of the sclera, and the size of the openings through which the sclera is exposed to the vacuum. And applicant insists that the devices of Hellencamp and L'Esperance would be so poorly designed by those having ordinary skill in the art, even when they are directed to produce a device which yields the very same effects which applicant touts in the originally filed disclosure as responsible for the superior performance of the instant device (e.g. uniform distribution of the vacuum), that they would not yield this performance, yet the instant disclosure, devoid of any discussion of vacuum level; minimum or maximum widths or depths of the grooves; diameter of the suction channel opening in the grooves; or range of scleral stiffness for normal sclera, is somehow magically enabling to prevent the clogging of the tiny suction channel, when the disclosures of Hellencamp and L'Esperance, devoid of the very same information are not. With regard to the use of lid speculum, as set forth above, the L'Esperance device has a "low profile" portion of the membrane protruding beyond the annular chamber and thus also does not require a lid speculum to the same extent the claimed device does not.

The bulk of the remainder of applicant's arguments merely rephrase the assertions of the declaration and applicant is referred to the responses to those portions of the affidavit set forth above for the responses to those portions of applicant's remarks.

The remainder of applicant's remarks will now be responded to. Applicant makes ereference to "the strange and improper position of advocating for the prior art" (instant response, the paragraph beginning on page 13) the examiner would be interested to review any citation applicant has regarding the impropriety of such "advocacy" as it has been practiced by the examiner in the instant prosecution. If by this applicant is asserting that it is improper for the examiner to extend the presumption of validity to the claims of an issued U.S. Patent, the examiner must vigorously disagree. If by this applicant is referring to something else, the examiner respectfully requests that applicant elucidate, as what is being referred to is not clear. With respect to the numbered points associated with the paragraph beginning on page 13, the examiner is relying only on the enabling disclosures of L'Esperance and Hellencamp, and basic physics. If the passages of Hellencamp become clogged, there will be no transmission of the vaccume force from one side of the clog to the other. If there is no vacuum force transmitted to the sclera, the eye will not be fixed, as required by the claims of the references. Applicant can determine this empirically by taking a vacuum cleaner hose and, after turning on the vacuum cleaner, placing the hose against a wall. Placing the hand on the opposite side of the wall will quickly reveal that no vacuum is transmitted through the clog (in this case the wall). No affidavit is believed necessary for this, however if applicant requires, the examiner can perform this experiment and submit the results in affidavit form. With regard to the second point, the examiner is not sure what applicant might consider "damage", however, Hellencamp *specifically states* that the "vacuum assembly is structured to apply a suction force which is sufficient to attach the positioning segment to the eyeball...while not being so strong as to cause damage to the eyeball". With regard to the third point, the examiner has taken no official notice with

respect the "high profile" or "low profile" devices, since no such limitation has been present in any claim that the examiner's responses which applicant is commenting on have addressed.

Moving on to other points not addressed on the affidavit, at page 16, applicant asserts that the examiner is indulging in impermissible hindsight. The examiner must respectfully disagree. As already set forth, the examiner is relying on the fact that the level of ordinary skill in the art is the same both for the artisan constructing a working device based on applicant's disclosure and on the artisan constructing the devices of L'Esperance and Hellencamp. With regard to applicant's assertion that that L'Esperance teaches away from the instant invention because L'Esperance "specifically teaches the **requirement** of using a lid speculum" (emphsis added), the examiner respectfully suggests that applicant has misread the L'Esperance reference. A careful reading of column 3 of this reference reveals the statement that the recited procedure constitutes "[P]preferred pre-operative (i.e., pre-surgery) procedural steps". As applicant is well aware, references are not limited only to their preferred embodiments. Thus these arguments are not convincing. With regard to the Curtin reference, it is the examiner's view that element 128 in Figure 1 of Curtin is clearly an "adjustment arm" within the broadest reasonable interpretation of the term. Curtin specifically discloses that "position of the tube 128 is adjustable with respect to the post 132 along the pathway indicated by arrows 134" (see column 5, lines 57-59) and in the immediately preceding sentence, tube 128 is described as "rigid". Thus clearly adjustment of the tube will cause adjustment of the ring, and any argument based on the premise that the ring is not adjustable must fail.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the ncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine the claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "convex" in the claims is apparently used by the claim to mean "having a surface which is somehow configured to be inwardly directed", while the accepted meaning is "curved or rounded like the exterior of a sphere or circle". The term is indefinite because the specification does not clearly redefine this term. Similarly the term "low profile" as used in claim 22 is indefinite, as it's meaning is unclear. While the drawings purport to show a "low profile" device, the cross-section shown in Figure 4 clearly shows a device, the total height of which is greater than one half the diametric extent thereof. This cross section does not show either the X- or Y-translation members, which add substantially to the total height of the device. It is unclear how such a device can "fit comfortably under the eyelid". Claim 22 is also indefinite because the exact meaning of the term "the profile of the eye fixation portion is substantially narrow" is unclear, this term lacks positive antecedent basis in the originally filed disclosure.

Claims 1, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp. Both L'Esperance (EP '127) and Hellenkamp teach a device and method as claimed except for the criss-cross passages. It would have been obvious to the artisan or ordinary skill to employ criss-cross channels in the devices and methods of L'Esperance (EP '127) or Hellenkamp, since this is another configuration that would serve to distribute the vacuum force and thus provides no unexpected result, and to discontinue the vacuum and reposition the apparatus if it is not centered on the cornea, since proper positioning of the corneal flap is critical for refractive surgery, official notice of which is hereby taken, thus producing a device and method such as claimed.

Claims 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp as applied to claims 1, 11, and 12 above, and further in combination with Curtin. Curtin teaches the use of adjustment arms on eye fixation devices. It would have been obvious to the artisan of ordinary skill to employ adjustment arms on the devices of L'Esperance (EP '127) or Hellenkamp, since these can be used to adjustably position the device, which is necessary due to the fact that eyes of different individuals will be in different relative locations, thus producing a device and method such as claimed.

Claims 3/1, 3/2, 4/3/1, 4/3/2, 7/4/3/1, 7/4/3/2, 8/7/4/3/1, 8/7/4/3/2, 14-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp as applied to claims 1, 11, and 12 above, and further in combination with Curtin and Clark et al. Curtin teaches the use of translation rods and adjustment knobs to allow the adjustment in 3 dimensions of an ophthalmic surgical instrument. Clark et al teach employing X- and Y-axis adjustment mechanisms on eye fixation devices. It would have been obvious to

the artisan of ordinary skill to employ the X- and Y-axis adjustment mechanisms on the devices of L'Esperance (EP '127) or Hellenkamp, since these can be used to position the device, or alternatively to employ the modified tissue/vacuum interface of L'Esperance (EP '127) or Hellenkamp in the device of Clark et al, since Clark et al provide no details of this aspect of the device, and in either case to provide the adjustment knob and rod configurations disclosed by Curtin, since Clark provides no details of the manner in which the translational adjustment is effected, thus producing a device and method such as claimed.

Claims 5/3/1, 5/3/2, 6/4/3/1, 6/4/3/2, 9/7/4/3/1, 9/7/4/3/2, 10/8/7/4/3/1, 10/8/7/4/3/2, 17, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp in combination with Curtin and Clark et al, as applied to claims 3/1, 3/2, 4/3/1, 4/3/2, 7/4/3/1, 7/4/3/2, 8/7/4/3/1, 8/7/4/3/2, 14-16, 18, and 19 above, and further in combination with Olson et al. Olson et al teach the old and well known mechanical expedient of employing set screws to hold two elements in a fixed relation to each other while performing corneal surgery. It would have been obvious to the artisan of ordinary skill to employ docking screws, since these allow the fixation of devices in the adjustment mechanisms, of the combined devices and methods of L'Esperance (EP '127) or Hellenkamp in combination with Curtin and Clark et al, since these can be used to fix the devices, relative to each other during coreal surgery, as taught by Olson et al, thus producing a device and method such as claimed.

Applicant's arguments filed January 16, 2007 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330